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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,287	10/01/2003	Richard Hochberg	Y03-076US	7077

7590

03/01/2006

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EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 03/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/676,287	Applicant(s) HOCHBERG, RICHARD	
	Examiner Barbara P. Badio, Ph.D.	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 13-38 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 13-38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. The rejection of claim 18 under 35 USC 112, first paragraph is withdrawn.
3. The rejection of claims 7-9, 11 and 12 under 35 USC 112, second paragraph is made moot by the cancellation of the instant claims.
4. The rejection of claims 1, 2, 5, 6 and 17 under 35 USC 112, second paragraph is withdrawn.

Double Patenting

5. The objection of claims 10-12 under 37 CFR 1.75 as being substantial duplicates of claims 4-6, respectively is withdrawn.

Claim Rejections - 35 USC § 102

6. The rejection of claims 7, 9 and 10 under 35 USC 102(b) over Jelinkova et al. is made moot by the cancellation of the instant claims.

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7. The rejection of claims 1, 3 and 4 under 35 USC 102(b) over Jelinkova et al. is withdrawn.

8. The rejection of claims 7 and 9 under 35 USC 102(b) over Agarwal et al. is made moot by the cancellation of the instant claims.

9. The rejection of claims 1 and 3 under 35 USC 102(b) over Agarwal et al. is withdrawn.

Claim Rejections - 35 USC § 103

10. The rejection of claims 13-17 under 35 USC 103(a) over Jelinkova et al. is withdrawn.

11. Claims 1-6 and 13-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van den Broek et al. (US 3,972,906).

Van den Broek et al. teach novel 11-substituted steroids of the estrane series such as 11 β -methoxymethyl-ethinyl-estradiol (see the entire article, especially col. 1, line 19 – col. 2, line 27). The reference teaches the compounds possess several properties including estrogenic and progestational properties and are useful in the treatment of estrogen-deficiency syndromes (see col. 2, lines 29-53).

The instant claims differ from the reference by reciting compounds not exemplified by the reference. For example, the instant claims recite compounds

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wherein when R is $-(CH_2)_nXR^4$, n is 1, X is O, R^4 is a C_{3-6} alkyl group. However, Van den Broek teaches a genus of compounds, including 11 β -methoxymethyl-ethinyl-estradiol, wherein R_8 can be a lower alkoxy group with 1-8 carbons such as methoxy and ethoxy (see col. 2, lines 24-28). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including that of the instant claims, because an ordinary artisan would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole.

Claims 13-18 and 33-38 further differ from the reference by reciting the treatment of the symptoms of menopause. However, because it is well known in the art that menopause is due to estrogen deficiency and the cited reference teaches the compounds are useful in the treatment of estrogen-deficiency syndromes, the utilization of the prior art compounds in treatment of symptoms of menopause would have been obvious to the skilled artisan at the time of the present invention.

In addition, as discussed in the previous Office Action, paragraph #10, the art teaches the utilization of estrogenic compounds in the treatment of menopausal symptoms, reduction of the risk of cardiovascular disease and breast cancer, thus, the utilization of the prior art estrogenic compounds in the treatment of diseases as recited by the instant claims would have obvious to the skilled artisan in the art at the time of the present invention.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

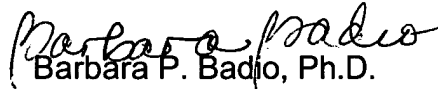
Telephone Inquiry

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB
February 27, 2006